Reproductive Technologies, Inc.
THE SPERM BANK OF CALIFORNIA

December 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S: Suitability Determination for Donors of Human Cellular and Tissues-Based Products

To whom it may concern,

We would like to submit comments on behalf of The Sperm Bank of California (TSBC) regarding the Food and Drug Administration's proposed rules on "Suitability Determination for Donors of Human Cellular and Tissue-Based Products." Since 1982 our sperm bank has been a leader in creating high standards for the semen banking industry. We have been working closely with the Department of Health Services in California in creating mandated standards for the banking of reproductive tissue. With this history in mind, TSBC strongly urges the FDA to make the following changes in the proposed rules:

1) Exempt sperm from screening for Creutzfeldt-Jakob Disease (CJD), a rare form of transmissible spongiform encephalopathies (TSE) since there is no report or scientific evidence of CJD transmission through semen.

2) Proposed section 1271.80(b) addresses the timing of collection of donor specimens for testing and proposes that specimens be collected 7 days prior to testing. It would be more practical for us to have at least 30 days, but no more than 90 days, between initial semen collection and clinical testing. There are natural fluctuations in semen sample parameters within the 72-day sperm cycle and introducing expensive tests prior to a complete assessment of a donor's fertility would be impractical. Extending the timeline as requested will provide us with the necessary time for adequate analysis of a donor-in-screening's fertility potential.

3) TSBC supports the inclusion of low-risk men who have sex with men (MSM) as both directed and anonymous sperm donors. We believe that recipients should be made aware of donor risk behaviors, test results, and be allowed to choose MSM donors knowingly. It is our hope that the impending FDA guidance document will not exclude these men from donating semen.

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4) We would like to ask the FDA to use a less value-laden term for MSM donors than "unsuitable." Although we understand that it is necessary to distinguish between donors with various risk behaviors, a less objectionable term would better reflect the FDA's desire to be inclusive in its regulations. Perhaps a term such as "restricted use" may be more appropriate.

Thank you for your consideration of the above-mentioned items. Please feel free to call upon us for any assistance we may provide as you consider suggested revisions.

Sincerely,

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Executive Director
The Sperm Bank of California

Benjamin Major, MD, MPH
Medical Director
The Sperm Bank of California

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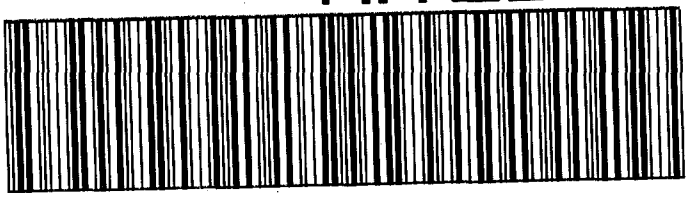

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